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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,997	02/05/2004	Kjell Malmlof	5904.214-US	5384
23650	7590	12/15/2005	EXAMINER	
NOVO NORDISK, INC. PATENT DEPARTMENT 100 COLLEGE ROAD WEST PRINCETON, NJ 08540			AUDET, MAURY A	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 12/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/772,997

Applicant(s)

MALMLOF ET AL.

Examiner

Maury Audet

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-11, 14 and 17-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-6, 8-11 and 14 is/are allowed.
- 6) ☒ Claim(s) 17-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>08/22/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Drucker et al. (US 6,051,557).

Drucker et al. teach pharmaceutical compositions comprising GLP-2 or analogs thereof with GH (claims 20-21, entire document), and describes the similarity of GLP-1 to GLP-2 (col. 1). Drucker et al. does not expressly teach GLP-1 with GH.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use GLP-1 as the analog of GLP-2 in Drucker et al., based on the structural similarity of the two compounds, and the ability of GLP-1 to serve as an analog of GLP-2.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

The rejection of claim 17 and new claim 18 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 8, and 18 of U.S. Patent No. 6,458,924 B2 ('924", Common Assignee), is maintained for the reasons of record. Applicant's arguments have been considered but are not found persuasive. Again, although the conflicting claims are not identical, they are not patentably distinct from each other because the

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'924 patent teach the use of GLP-1 (remains obvious to use even if '924 only used similar derivatives) in a composition with an antiobesity agent (e.g. growth hormone, col. 155, lines 33-40 "antiobesity agent"; Applicant's argument bears no weight, '924 specification teaches GH as a contemplated anti-obesity agent). Although the claims do not expressly claim that the composition is formulated for injection, this is readily obvious since the specification describe the compositions may be formulated for injection (col. 157, lines 13-25). As to new claim 18, even though it was previously remarked as an aside that the '924 claims are drawn to compositions of GH with GLP-1, but not drawn to methods of using GH with GLP-1, for appetite suppression; the new method claim 18 is so identically claimed to include all the limitations of the method, that the claim language of the composition necessarily renders the present method claim 18 obvious thereto (for the same reasons discussed above).

Allowable Subject Matter

Claims 1-6, 8-11, and 14, as amended to overcome the previously cited art and in light of applicant's arguments thereto, are not reasonably taught or suggested by the prior art of record. Namely, a method of suppressing appetite in a mature mammal comprising a composition that with an appetite-suppressing effective amount of growth hormone, with the "negative limitation" that the composition is completely free (with no language to the contrary) of other appetite suppressing agents, satiety-inducing agents, and anti-diabetic agents, was not found to be reasonably taught or suggested by the prior art of record. Namely, the art consistently teaches similar compensations, all contemplating the use of the latter.

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Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

No claims are allowed.

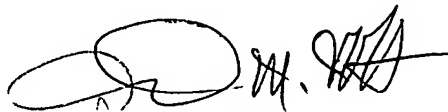
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

MA, 12/10/2005


DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 12857